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(71) Applicant(s)
Reckitt Benckiser (UK) Limited
(Incorporated in the United Kingdom)
103-105 Bath Road, SLOUGH, Berkshire, SL1 3UH, United Kingdom

(72) Inventor(s)
Malcolm Tom McKechnie
Geoffrey Robert Hammond
Steven Poile

(74) Agent and/or Address for Service
Elizabeth Anne Dickson
Reckitt Benckiser plc, Group Patents Department, Dansom Lane, HULL, HU8 7DS, United Kingdom

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(54) Abstract Title

Aerosol delivery system driven by hydrostatic pressure from osmotic or hydrogel swelling

(57) Hydrostatic pressure for driving a product from an aerosol container 1 is generated by an expandable material in the form of an osmotically effective agent and/or a swellable hydrogel. In operation, fluid permeates through a semi-permeable membrane 9 and is absorbed by the expandable material. The expandable material may be separated from the product to be dispensed by a piston, or by a flexible, impermeable membrane 5, or it may be contained in a bag 14 made of a flexible, semi-permeable membrane 15 disposed in a chamber together with the product. The fluid source may be external to the container, such as water in a bowl or in a cistern, or it may be held within the container 1 and may be separated from the expandable material by an impermeable membrane 23 which must be ruptured to activate the aerosol. Dispensing is through an aerosol valve 7 which may be actuated either manually or automatically when a predetermined pressure in the container is reached.

Fig.3.

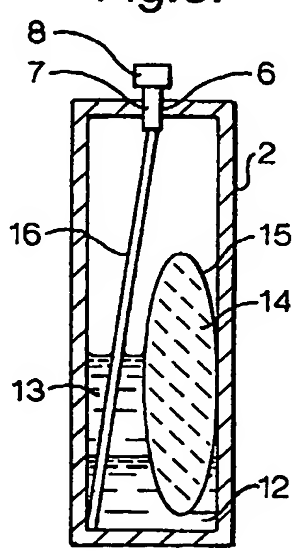
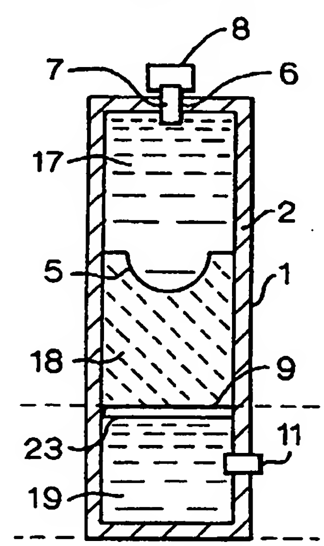


Fig.7 A.



At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

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Fig.1.

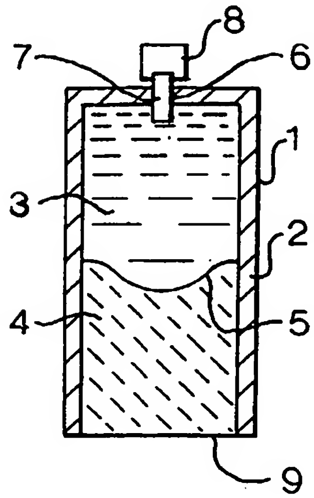


Fig.2.

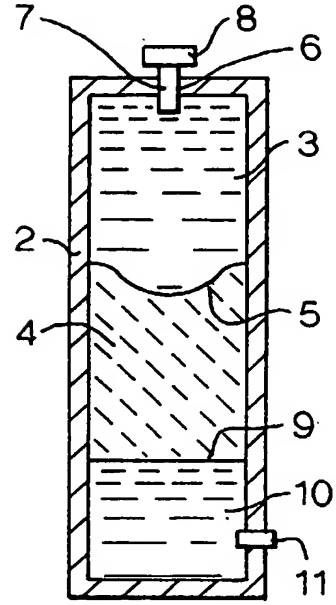


Fig.3.

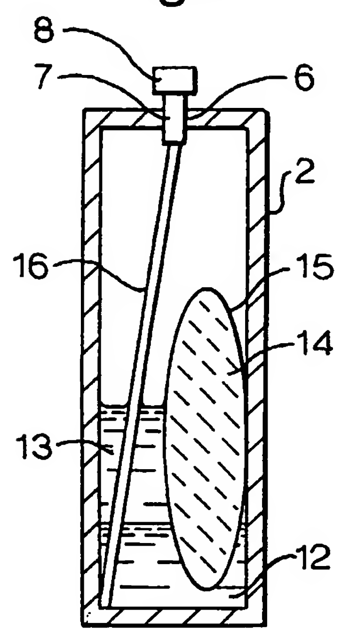


Fig.4 A.

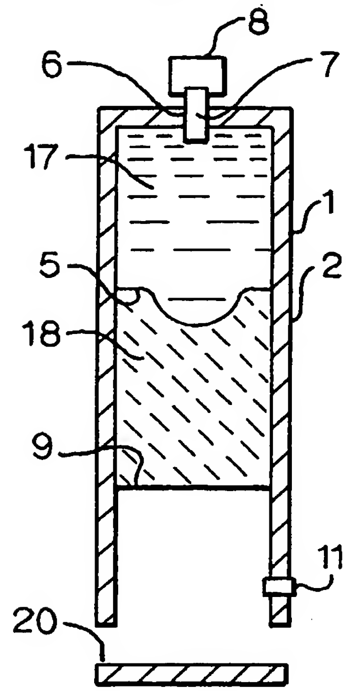


Fig.4 B.

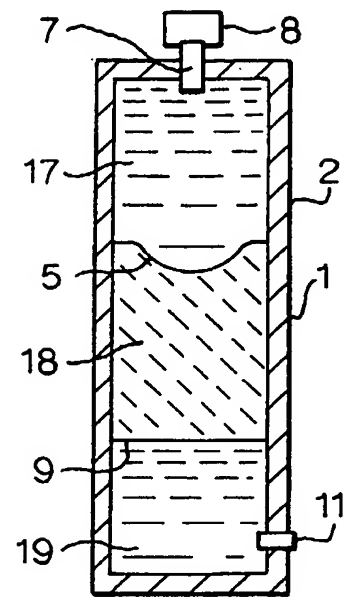


Fig.5 A.

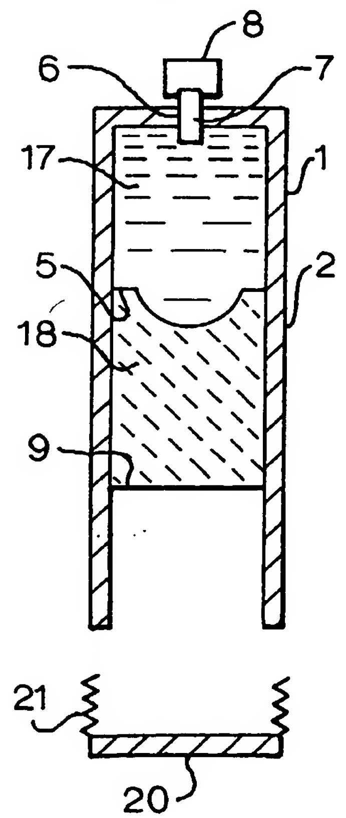


Fig.5 B.

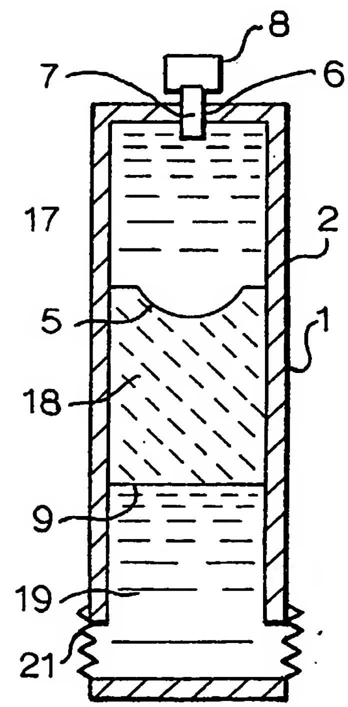


Fig.6 A.

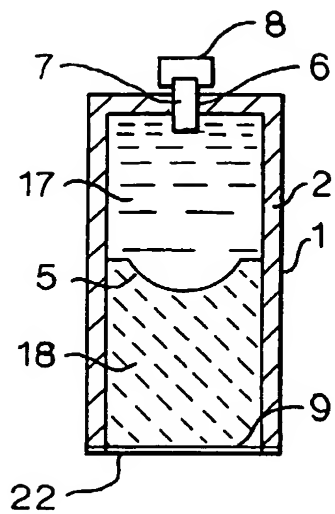


Fig.6 B.

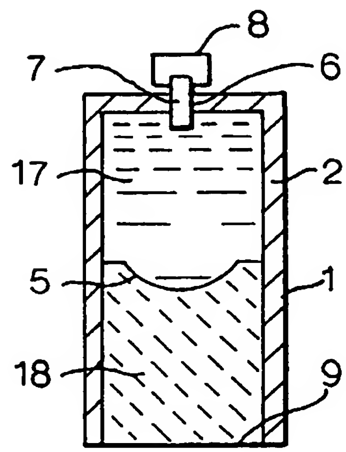


Fig.7 A.

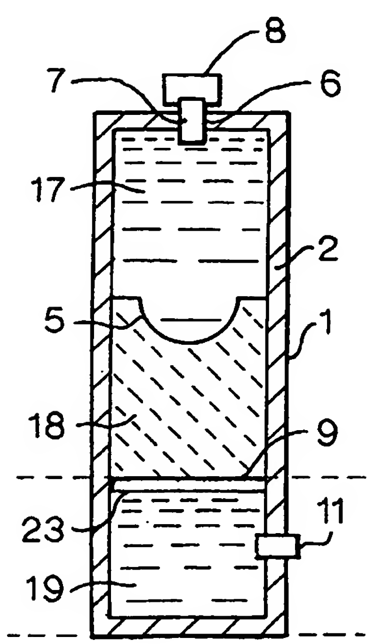
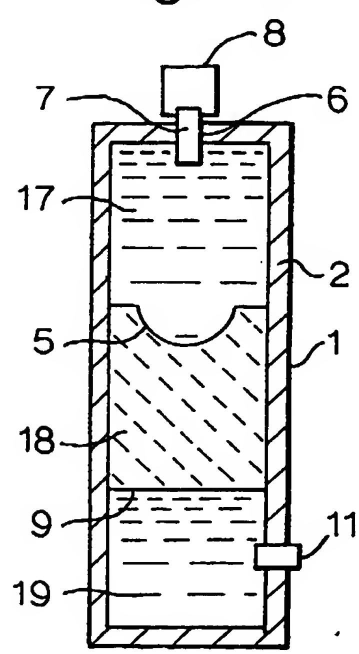


Fig.7 B.



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Device

The present invention provides an aerosol delivery system driven by hydrostatic pressure from an osmotic or hydrogel swelling device.

The use of aerosol delivery systems for the delivery of active agents is well known for a broad range of applications from personal care to surface cleaning to air perfuming. Conventional aerosol delivery systems rely upon hydrostatic pressure being introduced to the device during manufacture to enable expulsion of the contents upon demand during use. Generally such hydrostatic pressure has been applied by the introduction of gaseous propellants under pressure during manufacture, for example air or butane. The disadvantage of such systems is that the internal pressure decreases as the system is used, reducing the delivery rate of the active agents. There can also be problems when inflammable propellants are used. Furthermore the manufacturing process is expensive because of the pressurised product. A solution to these problems has been sought.

According to the invention there is provided an aerosol delivery system comprising a container defining a chamber for a product to be delivered, an outlet from the chamber through which product may in operation by delivered, a valve for controlling passage of product through the outlet and a pump for pressurising product to be delivered, wherein the pump comprises an expandable material which, in operation, may be expanded to provide the pressure for pressurising product to be delivered, the expandable material being

an osmotically effective agent and/or a swellable hydrogel and being disposed on one side of a semi-permeable membrane through which, in operation, fluid may be absorbed by the expandable material to expand it and thereby generate an osmotic pressure.

The expandable member may apply pressure to the active agent via either an impermeable membrane or a piston.

Suitable materials for use as a swellable hydrogel include polymeric materials optionally blended homogeneously or heterogeneously with osmotically effective agents. The polymeric material is optionally of plant, animal or synthetic origin. The material interacts with water or a biological fluid by absorbing the water or fluid and swelling or expanding to an equilibrium state. The polymeric material preferably exhibits the ability to retain a significant fraction of imbibed fluid in its polymeric molecular structure.

Preferably the polymeric material is a gel polymer that can swell or expand to a very high degree; for example it can have a 2- to 50-fold volume increase. A suitable gel polymer is a swellable, hydrophilic polymer (or an osmopolymer) which is optionally either non-cross-linked or lightly cross-linked. The cross-links can be covalent, ionic or hydrogen bonds so that the polymer possesses the ability to swell in the presence of fluid but does not dissolve in the fluid.

A polymeric material suitable for use in the expandable member is, for example, a poly(hydroxyalkylmethacrylate) having a molecular weight of from 5,000 to 5,000,000; poly(vinyl pyrrolidone) having a molecular weight of from 10,000 to 360,000; an anionic and/or cationic hydrogel; a poly(electrolyte) complexe; poly(vinyl alcohol) having a low acetate residual; a swellable mixture of agar and carboxymethyl cellulose; a swellable composition comprising methyl cellulose mixed with a sparingly cross-linked agar; a water-swellable copolymer produced by a dispersion of finely divided copolymer of maleic anhydride with styrene, ethylene, propylene or isobutylene; a water-swellable polymer of N-vinyl lactams; a swellable sodium salt of carboxymethyl cellulose.

Alternatively the polymeric material could be a gelable, fluid-imbibing and -retaining polymer such as a pectin having a molecular weight ranging from 30,000 to 300,000; a polysaccharide such as agar, acacia, karaya, tragacenth, algins and guar; an acidic carboxy polymer or its salt derivative such as one sold under the trade name Carbopol(RTM); a polyacrylamide; a water-swellable indene maleic anhydride polymer; a polyacrylic acid having a molecular weight of 80,000 to 200,000 such as one sold under the trade name Good-rite(RTM); a polyethylene oxide polymer having a molecular weight of 100,000 to 5,000,000 such as one sold under the trade name Good-rite(RTM); a starch graft copolymer; an acrylate polymer with water absorbability of about 400 times its original weight such as one sold under the trade name Aqua-Keep(RTM); a diester of polyglucan; a mixture of cross-linked poly(vinyl

alcohol) and poly (N-vinyl 2 pyrrolidone); poly(ethylene glycol) having a molecular weight of 4,000 to 100,000.

Other suitable polymer materials for use as the expandable member are those disclosed in U.S. Pat Nos. 3,865,108, 4,002,173, 4,207,893, 4,220,152, 4,327,725 and 4,350, 271, all of which are incorporated herein by reference, and in Scott et al, Handbook of Common Polymers, CRC Press, Cleveland, Ohio (1971).

The osmotically effective agent is in general an osmotically effective solute which is soluble in fluid imbibed into the expandable member such that there is an osmotic pressure gradient across the semipermeable membrane against the fluid source. A suitable osmotically effective agent is, for example, magnesium sulphate, magnesium chloride, sodium chloride, lithium chloride, potassium chloride, potassium sulphate, sodium sulphate, sodium phosphate (including hydrates thereof), mannitol, urea, sorbitol, inositol, sucrose, dextrose, lactose, fructose, glucose, magnesium succinate, sodium carbonate, sodium sulphite, sodium bicarbonate, potassium acid phthalate, calcium bicarbonate, potassium acid phosphate, raffinose, tartaric acid, succinic acid, calcium lactate or mixtures thereof. The osmotic pressure in atmospheres (atm) of the osmotically effective agents suitable for use in the invention must be greater than zero atm, generally from 8 atm up to 500 atm, or higher.

The solution of the osmotically effective agent exhibits an osmotic pressure gradient against the fluid source, and is preferably a saturated aqueous salt

solution. To maintain the solution saturated and therefore to achieve a constant osmotic pressure throughout operation of the dispenser, the expandable member containing the solution also contains an excess of the osmotically effective agent in solid form. The amount of the excess osmotically effective agent depends on the size of the system and the amount of product to be delivered. The excess solid can be in the form of dispersed particles or, preferably, in the form of a pellet. The solution can initially be a solution of the same or of an osmotically effective agent different from the solid excess agent.

The semi-permeable membrane is permeable to water but impermeable to the osmotically effective compound. Examples of suitable semi-permeable membranes include semipermeable homopolymers or copolymers. For example the semipermeable membrane is based on a cellulose ester, cellulose monoester, cellulose diester, cellulose triester, cellulose ether, cellulose ester ether; mono-, di- and tri-cellulose alkanylate; mono-, di- and tri alkenylate; and/or mono-, di- and tri-aroylate. Suitable examples of cellulose esters include cellulose acylate, cellulose diacylate, cellulose triacylate, cellulose acetate, cellulose diacetate, cellulose triacetate.

The cellulose polymers suitable for use as the semipermeable membrane have a degree of substitution (D.S.) on their anhydroglucose unit from greater than zero to 3. The "degree of substitution" is the average number of hydroxyl groups originally present on the anhydroglucose unit which have been replaced by a substituting group or converted into another group.

The anhydroglucose unit can be partially or completely substituted with groups such as acyl, alkanoyl, aroyl, alkyl, alkenyl, alkoxyl, halogen, carboalkyl, alkylcarbamate, alkylcarbonate, alkylsulfonate, and other semipermeable polymer forming groups which would be known to a person of skill in the art.

A suitable polymer for use as the semipermeable membrane includes a cellulose acetate having a D.S. of 1.8 to 2.3 and an acetyl content of 32% to 39.9%; cellulose diacetate having a D.S. of 1 to 2 and an acetyl content of 21% to 35%; and/or cellulose triacetate having a D.S. of 2 to 3 and an acetyl content of 34% to 44.8%. More specifically, suitable cellulosic polymers include cellulose propionate having a D.S. of 1.8 and a propionyl content of 38.5%; cellulose acetate propionate having an acetyl content of 1.5% to 7% and a propionyl content of 39% to 42%; cellulose acetate propionate having an acetyl content of 2.5% to 3%, an average propionyl content of 39.2% to 45% and a hydroxyl content of 2.8% to 5.4%; cellulose acetate butyrate having a D. S. of 1.8; an acetyl content of 13% to 15% and a butyryl content of 34% to 39%; cellulose acetate butyrate having an acetyl content of 2% to 29.5% a butyryl content of 17% to 53% and a hydroxyl content of 0.5% to 4.7%; cellulose triacylates having a D.S. of 2.9 to 3, such as cellulose trivalerate, cellulose trilaurate, cellulose tripalmitate, cellulose trioctanoate, and cellulose tripropionate; cellulose diesters having a D.S. of 2.2 to 2.6, such as cellulose disuccinate, cellulose dipalmitate, cellulose dioctanoate, and cellulose dicarpylate; cellulose propionate morpholinbutyrate; cellulose acetate butyrate; cellulose acetate

phthalate; mixed cellulose esters, such as cellulose acetate validate, cellulose acetate succinate, cellulose propionate succinate, cellulose acetate octanoate, cellulose valerate palmitate, cellulose acetate heptonate, and the like. Suitable semipermeable polymers are disclosed in U.S. Pat. No. 4,077,407, which is incorporated herein by reference, and they can be made by procedures described in Encyclopedia of Polymer Science and Technology Vol. 3. pages 325 -354, Interscience Publishers Inc., New York (1964).

Other suitable semipermeable polymers include cellulose acetaldehyde, dimethyl cellulose acetate; cellulose acetate ethylcarbomate; cellulose acetate methylcarbomate; cellulose dimethylamionacetate; a cellulose composition comprising cellulose acetate and hydroxypropylmethylcellulose; a composition comprising cellulose acetate and cellulose acetate butyrate; a cellulose composition comprising cellulose acetate butyrate and hydroxypropylmethylcellulose; semipermeable polyamides; semipermeable polyurethanes; semipermeable polysulfanes; semipermeable sulfonated polystyrene; crosslinked selectively semipermeable polymers formed by the coprecipitation of a polyanion and a polycation as disclosed in U.S. Pat. No. 3,173 876, 3,276,586, 3,541,005, 3,541,006 and 3,546,142, all of which are incorporated herein by reference; selectively semipermeable silicon rubbers; semipermeable polymers as disclosed by Loeb and Sourirajan in U.S. Pat. No 3,133,132, incorporated herein by reference, semipermeable polystyrene derivatives; semipermeable (polysodiumsytrenesulfonate); semipermeable poly(vinylbenzyltrimethyl) ammonium chloride

semipermeable polymers exhibiting a fluid permeability of from 10^{-1} to 10^{-7} (cc.mil/cm^{2}hr-atm) expressed as per atmosphere of hydrostatic or osmotic pressure difference across a semipermeable wall. The polymers are known to the art in U.S. Pat. Nos. 3,845,770, 3,916,899 and 4,160,020, all of which are incorporated herein by reference; and in J.R. Scott and W.J. Roff, *Handbook of Common Polymers*, CRC Press, Cleveland, Ohio, (1971).

The semipermeable membrane is preferably supported in such a way that it is substantially inflexible such that its shape and position do not change as the expandable material expands. This is in order that the pressure generated in the system by the expandable material is not applied to the fluid source but instead to the product to be delivered.

Preferably the aerosol delivery system includes a flexible impermeable membrane disposed between the pump and product to be delivered. For example the flexible impermeable membrane might form a partition dividing the container into sub-chambers. As an alternative to a flexible impermeable membrance the pump and product to be delivered may be separated by a piston.

In general the impermeable membrane must be impermeable to water and the osmotically effective agent. Suitable impermeable materials include polyethylene, compressed polyethylene fine powder, polyethylene terephthalate (such as that marketed under the name Mylar (RTM)), plasticized polyvinyl chloride, metal-foil polyethylene laminates, neoprene rubber, natural gum rubber and rubber hydrochloride such as

that marketed under the name Pliofilm. These materials are preferably flexible, insoluble and chemically compatible with the product to be delivered. Additional suitable materials include polystyrene, polypropylene, polyvinyl chloride, reinforced epoxy resin, polymethylmethacrylate, or styrene/acrylonitrile copolymer.

The valve used in the aerosol delivery system according to the invention is optionally either manually operable or automatic. Where the valve is automatic, the pressure at which it operates is preferably variable. In general a suitable automatic aerosol valve is a pressure actuated valve capable of releasing the compressed contents of a reservoir in stages as the contents of the reservoir reach a pre-determined internal pressure. A suitable activation pressure for the valve is from 5 to 10 atmospheres, for example 7 atmospheres. The shut off pressure for the automatic valve may be for example a pressure which 1 atmosphere less than the activation pressure or a pressure which is about 90% of the activation pressure.

Where the aerosol delivery system according to the invention is provided with a semi-permeable membrane, the membrane is preferably covered by a rupturable impermeable membrane. This is in order that the initial activation of the system can be controlled by the user. Optionally the system is provided with means for rupturing the rupturable impermeable membrane, e.g. by making part of the container rotatable relative to the remainder.

A suitable container for use in the present invention is any container able to withstand being pressurised which are conventionally used in the art. Suitable materials for making the container include metal or plastic materials, for example aluminium, tin plate, polyethylene terephthalate (PET), polyethylene naphalate (PEN) or a PET/PEN mixture, or glass particularly with a plastics barrier layer.

A suitable product to be delivered by the system of the invention is, for example, a pesticide, herbicide, germicide, biocide, algicide, rodenticide, fungicide, insecticide, insect repellent, anti-oxidant, sterilant, plant growth promoter or inhibitor, preservative, anti-preservative, disinfectant, surface cleaning agent, enzyme digestant, air freshener, deodorant, antiperspirant, depilatory, antiseptic, polish, wax, odour neutraliser, laundry care agent, hair lacquer, topical skin treatment, catalyst, chemical reactant, fermentation agent, food, food supplement, nutrient, cosmetic, drug, vitamin, sex sterilant, fertility inhibitor or promoter, air purifier, and/or microorganism attenuator. A suitable drug is any physiologically or pharmacologically active substance that produces a localised or systemic effect in a non-human animal, human, avian and/or domestic, recreational or farm animal. The drug may be administrable by topical, oral, nasal, opthalmic, rectal and/or vaginal means.

The external fluid is preferably water. The external fluid source is either within the container or external.

The aerosol delivery system according to the invention can be activated either during manufacture or by the user when ready to use. For the system to be activated, the semi-permeable membrane of the expandable member needs to come into contact with a fluid source. The system may be activated:

a) during manufacture, by the introduction of the external fluid to the pump device prior to aerosol device closure; or

b) prior to first use by user, by:

- introduction of an external fluid source; or
- removal of an internal seal.

The aerosol delivery system according to the invention can be activated to release the active agent either manually or by automatic action. The flow of the fluid from the fluid source to the pump may be controlled by modification of the semipermeable membrane so that the time during which the system becomes repressurised following activation can be lengthened, if desired.

A further advantage of the invention is that it provides an aerosol delivery system which can be reactivated by the user.

For a better understanding of the invention and to show how the same may be carried into effect, reference will now be made, by way of example, to the accompanying drawings in which:-

Figure 1 diagrammatically shows in section an aerosol according to the present invention,

Figure 2 diagrammatically shows in section a modified form of the aerosol shown in figure 1,

Figure 3 diagrammatically shows in section a further modified form of the aerosol shown in figure 1,

Figures 4a and 4b show stages in the manufacture of the embodiment of figure 2,

Figures 5a and 5b show stages in the manufacture of a modified form of the aerosol shown in figure 2,

Figures 6a and 6b show stages in the manufacture of the embodiment of figure 1, and

Figures 7a and 7b show stages in the manufacture of a further modified form of the embodiment of figure 2.

Referring to Figure 1, a first embodiment of the invention comprises a container 1 having a substantially non-deformable water insoluble wall 2 defining a chamber divided into two sub-chambers 3 and 4 by means of a flexible impermeable membrane 5. The wall 2 defines an outlet 6 leading from sub-chamber 3. An aerosol valve 7 is disposed in the outlet 6 and is operable by means of a button 8. Product to be delivered is disposed in sub-chamber 3 and an expandable material is disposed in sub-chamber 4. Sub-chamber 4 is closed off at its end remote from the aerosol valve 7 by means of a substantially inflexible semi-permeable membrane 9. In operation, fluid from an external source (not shown) permeates through the semi-permeable membrane 9 by osmosis and/or other

hydration forces and is absorbed by the expandable material disposed in sub-chamber 18. This results in a pressure increase which is transmitted through the flexible impermeable membrane 5 to the product to be delivered in sub-chamber 3. This pressure may be released by depressing button 8 which opens the valve 7 enabling the product to be delivered to issue through the outlet 6 as a spray. As an alternative to manual activation of the valve 7, activation may be automatic. In this alternative, the valve 7 may open automatically when a predetermined threshold pressure is reached. The valve may remain open or may close automatically. Automatic closure may occur when the pressure falls below a certain predetermined pressure or after a certain predetermined time. Where the valve remains open the delivery is a one shot delivery and when the valve is closed a repetitive or pulsed delivery which depends for its cycle time on the time required for the pump to recharge as explained above to an acceptable threshold pressure. A one shot delivery may be required for sanitary purposes and a repetitive pulsed system for a room air freshener where a new release of product to be delivered would generally be required at predetermined intervals. In the aforementioned sanitory application, the external source of fluid may be provided by the water in a cistern whereas, in the repetitive pulsed system, the aerosol may be stood in a bowl of water to provide fluid from an external source.

In Figures 2, 3, 4a, 4b, 5a, 5b, 6a, 6b, 7a and 7b corresponding parts to parts of Figure 1 are denoted by like reference numerals.

Referring to Figure 2, a second embodiment of the invention is the same as the embodiment of Figure 1 except that the fluid instead of being provided from an external source is incorporated as an integral part of the aerosol. Thus this second embodiment comprises a container 1 having a substantially non-deformable water-insoluble wall 2 defining a chamber which is divided into three sub-chambers 3, 4 and 10. Sub-chamber 3 contains the product to be delivered and is separated from sub-chamber 4 by means of a flexible impermeable membrane 5. Sub-chamber 4 contains an expandable material and is separated from sub-chamber 10 by means of a substantially inflexible semi-permeable membrane 9. Sub-chamber 10 contains fluid and is provided with a non-return valve 11. A hydrophobic porous sinter, e.g. in the form of a disc, could be used as an alternative to a non-return valve. The purpose of the non-return valve or the hydrophobic porous sinter is to allow passage of air into sub-chamber 10 without allowing the fluid in the chamber to escape. This is necessary to equalise the pressure in the chamber during operation of the aerosol. As an alternative to a valve or a porous sinter, the portion of the wall 2 which defines sub-chamber 10 could be made collapsible. As with the embodiment of Figure 1, the wall 2 defines an outlet 6 in which a valve 7, which may be operated by means of a button 8, is disposed. Operation is similar to that of the embodiment of Figure 1, the only difference being that the fluid permeates from the internal source 10 through semi-permeable membrane 9 to raise the pressure in sub-chamber 4. Again the manually operable valve may be made automatic in the same way and for the same

purpose as the automatic valve alternative described with reference to Figure 1.

Referring to Figure 3, a further embodiment comprises a container having a substantially non-deformable water insoluble wall 2 which defines an outlet 6 in which an aerosol valve 7 operable by means of a button 8 is disposed. The lower part 12 of the container accommodates the product to be delivered and the upper part 13 fluid. There is no physical barrier between the fluid and the active agent. Suspended in the fluid and active agent is a bag 14 made of a flexible semi-permeable membrane 15 and containing an expandable material. In this embodiment fluid permeates by osmotic action through the semi-permeable membrane of the bag 14 causing the bag to expand to pressurise the product to be delivered. On operating the aerosol valve 7 product to be delivered may then be expelled from the container via a tube 16 leading to the outlet 6. As with the previous embodiments, and for the same or similar reasons, the aerosol valve may be manual or automatic, and either single one shot release or multiple releases may be provided for. In all embodiments, the minimum time between successive releases will depend upon the ability of the system to repressurise after each release. This in turn will depend upon the expandable material chosen and its characteristics.

Figure 4a and 4b illustrate a mode of manufacture for the embodiment of Figure 2. The product to be delivered 17, impermeable membrane 5, expandable material 18, flexible semi-permeable membrane 9 and fluid 19, are introduced into the container 1 in turn

following which base 20, which is initially separate, is added and sealed in position to produce the finished product. The container 1 has a substantially non-deformable water insoluble wall 2 which defines an outlet 6 in which an aerosol valve 7 operable by means of a button 8 is disposed. The container 1 is also provided with a non-return valve 11.

Figures 5a and 5b show a mode of manufacture similar to that of Figures 4a and 4b but where base 20 is connected, e.g. by a screw thread, to the remainder of container 1 by means of a collapsible bellows portion 21. This enables the fluid to be pressurised externally by the consumer after manufacture and sale. In particular the use of collapsible bellows obviates the need for a non-return valve 11. In all other respects manufacture is as in the embodiment of Figures 4a and 4b.

Figures 6a and 6b show a mode of manufacture for the embodiment of Figure 1. In this embodiment, fluid to activate the osmotic agent and/or swellable hydrogel is not provided at the manufacturing stage, but is supplied by the customer, for example, in the manner already described. Advantageously, after introducing the product to be delivered 17, impermeable membrane 5, and expandable member 18, the container is closed off at its base by the semi-permeable membrane 9. However, to avoid unwanted absorption through this membrane 9 after manufacture but before delivery to the customer, the membrane needs protection. This is provided by an impermeable adhesive strip 22 which may be removed by the customer prior to placing the semi-permeable membrane 9 in contact with an external source of fluid.

Claims

1. An aerosol delivery system comprising a container defining a chamber for a product to be delivered, an outlet from the chamber through which product may in operation be delivered, a valve for controlling passage of product through the outlet and a pump for pressurising product to be delivered, wherein the pump comprises an expandable material which, in operation, may be expanded to provide the pressure for pressurising product to be delivered, the expandable material being an osmotically effective agent and/or a swellable hydrogel and being disposed on one side of a semi-permeable membrane through which, in operation, fluid may be absorbed by the expandable material to expand it and thereby generate an osmotic pressure.

2. An aerosol delivery system as claimed in claim 1 wherein the semi-permeable membrane is in the form of a bag.

3. An aerosol delivery system as claimed in claim 1 or 2, in which the semi-permeable membrane is covered by a rupturable impermeable membrane.

4. An aerosol delivery system as claimed in claim 3, in which means are provided for rupturing the rupturable impermeable membrane.

5. An aerosol delivery system as claimed in claim 4, in which part of the container is made rotatable relative to the remainder to provide means for rupturing.

6. An aerosol delivery system as claimed in any one of the preceding claims, in which a flexible impermeable membrane is disposed between the pump and product to be delivered.

7. An aerosol delivery system as claimed in claim 6, in which the flexible impermeable membrane forms a partition dividing the container into sub-chambers.

8. An aerosol delivery system as claimed in any one of the preceding claims, in which the valve is manually operable.

9. An aerosol delivery system as claimed in any of claims 1 to 7, in which the valve is automatic.

10. An aerosol delivery system as claimed in claim 9, in which the pressure at which the valve operates is variable.

11. An aerosol delivery system substantially as hereinbefore described with reference to the drawings.

12. A method of manufacturing an aerosol delivery system substantially as hereinbefore described with reference to drawings 4a, 4b, 5a, 5b, 6a, 6b, 7a and 7b.